K130349

510(k) Summary - Freemie® Breast Pump Collection System

Submitter	DAO Health 1345 Easy Ln El Dorado Hills, California, 95762
Date Prepared	April 1, 2013 (original) August 8, 2013 (S002)
Contact Person	Dan Garbez Phone: 916-339-7388 FAX: 877-869-1973 e-mail: dan@daohealth.com
Device Trade Name	Freemie® Breast Pump Collection System
Classification Name	Powered Breast Pump
Device Classification	Regulatory Class: Class II (two) Product Code: 85 HGX 884.5160
Predicate Device(s)	Freemie Breast Pump Collection System (K111411) Medela® Pump in Style Advanced® Breastpump (K031614)
Performance Standards	Performance standards have not been promulgated for powered breast pumps.
Intended Use	The Freemie breast pump collection system is intended to be used in conjunction with an approved powered breast pump for the purpose of expressing human milk.

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Device Description	The device is to be used by connection to an approved breast pump, and will be used in place of the pump's original breast milk collection equipment. The device has a funnel-shaped breast funnel, internal valve assembly and enclosing reservoir shaped like a bowl. Additional accessories, associated with the device to replicate the functional and performance characteristics necessary for use with some pump brands, will be sold separately but in conjunction with the sale of the Freemie when those specific brands are identified by the user. The Freemie device is designed to be supported within a woman's ordinary or nursing brassiere, and held in place there while the lactating woman is pumping. When the pump extracts milk, the milk flows out through the end of the funnel and enclosing valve system, where it gathers and is collected in the cup. When the lactating woman is done pumping, she turns off the pump, removes the Freemie from her brassiere and transfers the milk to a storage container for later use. The Freemie device is available with two cup variations. The first (identified as "Round" or "Standard") is similar in shape to the predicate Freemie (K111411). The second (referred to as "Shaped" or "Natural" or "Formed") is a shaped cup that is intended to approximate a shape that, for aesthetic purposes, more resembles the natural shape of a breast supported by an ordinary brassiere. Both variants are made from the same materials, function identically and use the same valve and funnel assembly and will be chosen by the user based on individual preference. The interfaces where the cup and cone variants attach to each other are identical. The Freemie will also be available in 3 funnel variants, a 25mm (similar to the predicate Freemie), identified by DAO Health as FG008 (Standard) and FG011 (Form Shape), and larger 28mm (FG009 for the Standard and FG012 for the Form Shape) and 32mm (FG010 for Standard and FG013 for the Form Shape) funnels. All funnel sizes are made from the same material, fit with either of the cup variants and use the same universal valve assembly.
Biocompatibility	The Freemie Breast Pump Collection System has passed all biocompatibility testing.
Performance Data	Performance testing was conducted to demonstrate Safety and Effectiveness and for comparison to the predicate device. Testing included: Breast Funnel Design, Compatible Pumps, Vacuum Performance and Capacity and Freedom from Leakage, Ability to be Supported.
Summary	The Freemie Breast Pump Collection System is constructed of similar materials, has a similar design and the same indications as the Predicate Device(s) and other currently marketed accessories for powered breast pumps. Bench and biocompatibility testing have demonstrated equivalence and the safety and effectiveness of the device.
Conclusion	The Freemie Breast Pump Collection System is substantially equivalent to the predicate devices and other currently marketed accessories for powered breast pumps.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 6, 2013

DAO Health
% Dan Garbez
Manager
1345 Easy Ln
El Dorado Hills, CA 95762

Re: K130349
Trade/Device Name: Freemie® Breast Pump Collection System
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: August 8, 2013
Received: August 13, 2013

Dear Dan Garbez,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130349

Device Name: Freemie® Breast Pump Collection System

Freemie Catalog/ Model Number	Cup Type	Funnel Size
FG008	Standard	25mm
FG009	Standard	28mm
FG010	Standard	32mm
FG011	Form Shape	25mm
FG012	Form Shape	28mm
FG013	Form Shape	32mm

Indications For Use: The Freemie breast pump collection system is intended to be used in conjunction with an approved powered breast pump for the purpose of expressing human milk.

Prescription Use _____ AND/OR Over-The-Counter Use __X____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Herbert P. Lerner -S